REMARKS

Claims 6 and 20 have been canceled. Claims 1 and 18 have been amended. No new matter has been added. Thus, claims 1 - 5, 7 - 19 and 21 - 24 are pending in this application. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

The amendment filed on 7/6/2006 stands objected to under 35 U.S.C. § 132(a) and 35 U.S.C. § 112, first paragraph, as introducing new subject matter. In view of the above amendments to claims 1 and 18, it is respectfully submitted that this rejection should be withdrawn. Specifically, the language that has been objected to by the Examiner has been removed from claims 1 and 18. Furthermore, the newly added language of a bypass element adapted "to introduce fluids into the catheter distally of the valve," in claim 1 is clearly supported by the Specification and corresponding Figures of the present application. (*See* Specification, ¶ 0018] - [0021], Figs. 1 - 3). Specifically, the Specification recites that the bypass element 108 "is sized so that it extends through the slit [and] past the flow control membrane 208 [...] so that the fluid exiting the orifice 114 [of the connector 100] is injected beyond the membrane 208, and cannot damage it." (*Id.* at ¶ [0020]). The Specification further states that flow through the device of the present invention is configured for "*injection* of a contrast media at elevated pressures into a patient's vascular system through a valved venous catheter," via an opening at a distal end of the bypass element which is inserted past the valve – i.e., "distally of the valve," as recited in amended claim 1. (*Id.* at ¶ [0017]). It is therefore respectfully submitted that there is ample support for the limitations added to claims 1 and 18 in both the Specification and in Figs. 1 - 3 of the present application and it is respectfully requested that the objection to the Specification and the 35 U.S.C. § 112, first paragraph rejection of claim 1 be withdrawn.

Claims 1 - 5, 7 - 8, 11 - 13, 18 - 19, 21 and 23 stand rejected under 35 U.S.C. § 102(b) or alternatively, under 35 U.S.C. § 103(a) as anticipated by U.S. Patent No. 5,125,893 to Dryden. ("Dryden").

Claim 1 recites a connector for injecting fluid to a catheter, comprising "an attachment

portion adapted to fluidly couple to a source of pressurized fluid" and "a bypass element fluidly connected to the attachment portion, the bypass element being adapted to open a valve of the catheter and to introduce fluids into the catheter distally of the valve" in combination with "*an overpressure control element adapted to maintain a pressure of fluid within the connector below a predetermined threshold level*."

It is respectfully submitted that Dryden fails to teach or suggest "*an overpressure control element adapted to maintain a pressure of fluid within the connector below a predetermined threshold level*," as recited in claim 1. It is first noted that the recited overpressure control element is a structural limitation indicative of an element sized and shaped for controlling a pressure of fluid within the connector to prevent an overpressure therein. Those skilled in the art will understand that this behavior is dictated by the structure of the element and is not simply a statement of an intended use or purpose for the device. There are many elements which would be structurally unsuitable for use as the recited overpressure control element (e.g., elements having substantially large lumens extending therethrough). It is therefore noted that the limitation of an "overpressure control element adapted to maintain a pressure of fluid within the connector below a predetermined threshold level" is a structural limitation. Furthermore, it is noted that the plain meaning of the term "overpressure control element" itself is structural – i.e., an element included in the device to prevent an overpressure state in the controller. (*See* MPEP § 2111.01). Accordingly, even if the "adapted to" limitation were to be removed from claim 1, the "overpressure control element" limitation alone would be sufficient to overcome the teachings of Dryden, as described in greater detail below.

The valve 35 of Dryden does not meet the limitations of the overpressure control element recited in claim 1. Specifically, the valve 35 of Dryden is described only as controlling an amount of irrigation fluid supplied to the catheter 28. Dryden makes absolutely no mention of any control of the pressure in the catheter 28, much less by the valve 35 which is described only as having a simple on/off functionality. (*See* Dryden, col. 2, ll. 55 - 56). Dryden neither shows nor suggests any valve for maintaining a pressure within a connector below a threshold level as recited in claim 1. It is respectfully submitted that the mere fact that the valve 35 facilitates the introduction of fluid into the catheter 28 is not sufficient to meet the limitation of controlling a pressure of fluid therewithin. The valve 35 is not configured to prevent an overpressure of fluid beyond any predetermined pressure threshold but rather, is taught as being opened to flow only

when suctioning is already being applied in the catheter 28, such that pressure buildup in the catheter 28 by the valve 35 is not possible. (*See* Dryden, col. 1, ll. 39 - 44). It is therefore respectfully submitted that the Examiner's statements regarding this functionality of the valve 35 are purely speculative and in no way supported by the disclosure of Dryden.

The Examiner has further asserted that it would have been obvious to have constructed the valve 35 as a pressure control element as claimed. (*See* 12/2/08 Office Action, p. 4). However, it is respectfully submitted that Dryden provides no basis to modify its device to include "an overpressure control element," as recited in claim 1. Specifically, the device of Dryden is directed to introduce fluid through the valve 35 simultaneously as suctioning occurs in order to dilute the lung secretions being suctioned. (*See* Dryden, col. 1, ll. 39 - 44). It is therefore evident that Dryden teaches away from a device where a fluid pressure can build up therewithin since fluid is only supplied in unison with a fluid withdrawal via the suction machine 13. (*Id.*, *See Also* col. 2, ll. 45 - 56). It is therefore submitted that one skilled in the art would behave no reason to modify the on/off valve 35 to enable it to perform an overpressure control function as recited in claim 1 since pressure buildup cannot occur with the fluid supply 12 connected to valve 35.

It is therefore respectfully submitted that Dryden fails to show or suggest a connector for injecting fluid to a catheter comprising "an overpressure control element adapted to maintain a pressure of fluid within the connector below a predetermined threshold level," as recited in claim 1 and that claim 1 is allowable over Dryden. Because claims 2 - 5, 7 - 8 and 11 - 13 depend from and, therefore, include the limitations of claim 1, it is respectfully submitted that these claims are allowable for at least the reasons stated above.

Amended claim 18 recites limitations substantially similar to amended claim 1, including "a pressure control element adapted to limit a fluid pressure within the coupler to a predetermined threshold level." It is therefore respectfully submitted that claim 18 and its dependent claims 19, 21 and 23 are therefore allowable over Dryden.

Claims 9 - 10, 22 and 24 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Dryden in view of U.S. Patent No. 6,375,637 to Campbell et al. ("Campbell"). In support of the rejection, the Examiner has stated that Dryden, teaches the device as claimed except for the

overpressure control element being an extension tube and having an external collection jacket disposed therearound. The Examiner references the Campbell device to overcome this deficiency. (*See* 12/02/08 Office Action, pp. 5 - 6).

As stated above in regard to claim 1 from which claim 9 - 10 depend, Dryden fails to teach or suggest the limitations of claim 1. Campbell fails to overcome the deficiencies of the Dryden device. It is therefore submitted that Dryden and Campbell, either alone or in combination, fail to teach or suggest the limitations of claim 1. Because claims 9 and 10 depend from and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Additionally, as stated above in regard to claim 18 from which claim 22 and 24 depend, Dryden also fails to teach or suggest the limitations of claim 18. Campbell fails to overcome the deficiencies of the Dryden device. It is therefore submitted that Dryden and Campbell, either alone or in combination, fail to teach or suggest the limitations of claim 18. Because claims 22 and 24 depend from and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claims 14 - 17 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Dryden.

Claims 14 - 17 depend from, and therefore include all of the limitations of claim 1. As noted above, Dryden fails to teach or suggest the limitations of claim 1. Thus, it is respectfully submitted that claims 14 - 17 are allowable for at least the same reasons stated above in regard to claim 1.

In light of the foregoing, Applicants respectfully submit that all of the now pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, and an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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